

### **REMARKS**

In the Office Action dated May 1, 2009, the Examiner requested a statement providing a complete address for Carl Reitz, objected to claim 5 for informalities, rejected claims 2-4 and 44 under 35 U.S.C. § 112, second paragraph, as being indefinite, rejected claims 1-37, 39, and 41-44 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,258,027 to Sternby ("*Sternby*"); and rejected claims 1-42 and 44 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,011,384 to Goux ("*Goux*").

By this reply, Applicant has amended claims 4, 6-17, 20-36, 44, and 46-59 and canceled claims 1-3, 5, 18, and 19. Applicant has also added new claims 60-62. New claim 60 includes features from previous claims 1 and 5. New claim 61 includes features from previous claims 1, 2, and 3. New claim 62 includes features from previous claims 1, 18, and 19. No new matter is added by this Reply.

### **Statement Regarding Address**

In the Office Action the Examiner states that "Applicant (Carl Reitz) has not given a post office address in the application." The Examiner requested a "statement over applicant's signature providing a complete post office address." (Office Action at 2.) Further to Applicant's conversation with Examiner Christian on August 3, 2009, Applicant will provide a corrected address at a later date.

### **Objection to Claim**

The Examiner objected to claim 5 for informalities. Applicant has canceled claim 5, and therefore the objection is moot.

**Section 112 Rejection**

The Examiner rejected claims 2-4 and 44 under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, the Examiner argues that Applicant has not used the appropriate form for alternative expressions. Although Applicant does not necessarily agree with the Examiner, Applicant has amended claim 44 to recite "consisting of." Claims 2 and 3 have been canceled, thereby rendering the rejection with respect to these claims moot. Finally, Applicant submits that claim 4 does not utilize an alternative expression, and therefore the rejection with respect to this claim should also be withdrawn.

**Section 102 Rejections**

Claims 1-37, 39, and 41-44 were rejected under 35 U.S.C. § 102(b) as being anticipated by *Sternby*. The Examiner contends that *Sternby* discloses a "blood treatment unit (Fig. 1) with a semi-permeable membrane (3) with first and second compartments for blood and treatment liquid (C10/L43-47) and a controller (17)." (Office Action at 3.) The Examiner further contends that claims 1-36:

are replete with functional and intended use language that does not structurally differentiate the controller. The controller of STERNBY is implicitly capable of manipulating the data from the sensor readings to determine the progress of the treatment . . . and directing treatment based on sensor readings and data calculations (see claims 26-49 of STERNBY).

(Office Action at 4.) The Examiner also rejected claims 1-42 and 44 under 35 U.S.C. § 102(b) as being anticipated by *Goux*. The Examiner once again argues that claims 1-

36 utilize functional language that does not structurally differentiate the controller. (See Office Action at 7.) Applicant disagrees.

It is well established that an "[a]pplicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought."

M.P.E.P. § 2173.01. Further, "[t]here is nothing inherently wrong with defining some part of an invention in functional terms." M.P.E.P. § 2173.05(g).

A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step.

M.P.E.P. § 2173.05(g).

Accordingly, the claims' recitation of a "controller being configured to . . ." should be examined and given patentable weight. In view of these remarks, Applicant respectfully requests reconsideration and reexamination of this application.

Additionally, *Sternby* and *Goux* do not disclose each and every feature of new claims 60, 61, and 62.

*Sternby* discloses a method for calculating dialysis efficiency. Specifically, *Sternby* discloses a device wherein:

the urea concentration measured by a urea monitor in the effluent dialysate solution from the dialyzer, is used for determining parameters of the dialysis as it progresses. These parameters are used for assessing the dialysis treatment on-line to determine the efficiency, the delivered dose, pre and post total urea masses in the body, the urea generation rate, the volume of distribution of urea in the body

(for example by taking a blood sample for determining the urea concentration in the blood), and still further parameters and variables as will become evident in the description to follow.

(Col. 12, lines 28-38.) Regarding new independent claim 60, *Sternby* does not disclose a "controller . . . configured to compare said calculated dialysis dose  $K \cdot T_{Ti}$  to at least a total dialysis dosage value  $K \cdot T_p$  to be achieved at the end of the treatment and to generate at least one output control signal responsive to said comparison for automatically controlling one or more operations performed by the equipment, the controller also being configured to determine at least one timing selected from the group consisting of an estimated remaining treatment procedure time  $T_{tr}$  and an estimated total treatment time  $T_{tot}$  required for achieving said prescribed total dialysis dosage value  $KT_p$ ," as recited in new independent claim 60.

With respect to new independent claim 61, *Sternby* does not disclose a controller configured to "compare said calculated significant parameter to at least a prescribed reference value for the same parameter, and generate at least one output control signal responsive to said comparison for automatically controlling a fluid removal rate from said second compartment," as recited in new independent claim 61.

With respect to new independent claim 62, *Sternby* does not disclose a controller configured to "determine a prescribed rate  $R$  by dividing said total weight loss  $W_{LP}$  to be achieved at the end of the treatment by said total dialysis dose value  $K T_p$  to be achieved at the end of the treatment, determine at time intervals during treatment: a parameter selected from the group consisting of an instantaneous clearance  $K_{Ti}$  measured at an elapsed treatment time  $T_i$  and a dialysance value  $D_{Ti}$  measured at an elapsed treatment

time  $T_i$ ; and controlling the rate of fluid removal from the second compartment of the blood treatment, said controlling comprising keeping said rate of fluid removal  $UF_{Ti}$  at time  $T_i$  substantially equal to the product of said prescribed rate  $R$  by the instantaneous clearance  $K_{Ti}$  or instantaneous dialysance value  $D_{Ti}$  measured at treatment time  $T_i$ ," as recited in new independent claim 62.

*Goux* discloses a method and a device for determining a parameter indicative of the progress of a blood treatment. Specifically, the method of *Goux* includes:

steps of flowing through the exchanger a treatment liquid having a concentration characteristic ( $C_d$ ) and of varying the value of the characteristic ( $C_d$ ) upstream of the exchanger for a time at the end of which the characteristic ( $C_d$ ) is returned to a nominal value. A plurality of values adopted by the characteristic ( $C_d$ ) downstream of the exchanger in response to the upstream variation is measured and stored in memory. The area ( $S_{out}$ ) of a downstream perturbation region is determined, which is bounded by a baseline and a curve representing the variation of the measured values with respect to time. Then, the parameter ( $D, K, Kt/v, C_{bin}$ ) indicative of the effectiveness of the treatment is calculated using the area ( $S_{in}$ ) beneath the upstream curve and an area beneath an upstream curve.

(Abstract.)

With respect to new independent claim 60, *Goux* does not disclose a "controller . . . configured to compare said calculated dialysis dose  $K \cdot T_{Ti}$  to at least a total dialysis dosage value  $K \cdot T_p$  to be achieved at the end of the treatment and to generate at least one output control signal responsive to said comparison for automatically controlling one or more operations performed by the equipment, the controller also being configured to determine at least one timing selected from the group consisting of an estimated remaining treatment procedure time  $T_{tr}$  and an estimated total treatment time

$T_{\text{tot}}$  required for achieving said prescribed total dialysis dosage value  $KT_p$ ," as recited in new independent claim 60.

With respect to new independent claim 61, *Goux* does not disclose a controller configured to "compare said calculated significant parameter to at least a prescribed reference value for the same parameter, and generate at least one output control signal responsive to said comparison for automatically controlling a fluid removal rate from said second compartment," as recited in new independent claim 61.

With respect to new independent claim 62, *Goux* does not disclose a controller configured to "determine a prescribed rate  $R$  by dividing said total weight loss  $W_{LP}$  to be achieved at the end of the treatment by said total dialysis dose value  $KT_p$  to be achieved at the end of the treatment, determine at time intervals during treatment: a parameter selected from the group consisting of an instantaneous clearance  $K_{Ti}$  measured at an elapsed treatment time  $T_i$  and a dialysance value  $D_{Ti}$  measured at an elapsed treatment time  $T_i$ ; and controlling the rate of fluid removal from the second compartment of the blood treatment, said controlling comprising keeping said rate of fluid removal  $UF_{Ti}$  at time  $T_i$  substantially equal to the product of said prescribed rate  $R$  by the instantaneous clearance  $K_{Ti}$  or instantaneous dialysance value  $D_{Ti}$  measured at treatment time  $T_i$ ," as recited in new independent claim 62.

Accordingly, new independent claims 60, 61, and 62 are allowable over *Sternby* and *Goux*. Claims 4, 6-17, and 20-59 are allowable at least due to their dependence from one of claims 60 and 61 and due to their recitations of additional patentable subject matter.

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.


Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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By

  
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